

REMARKS

Claims 7, 8, and 22-26 remain active in this application.

Applicants wish to thank Examiner Afremova for the helpful and courteous discussion with the Applicants' undersigned representative on May 13, 2004. During this discussion, various amendments and arguments were discussed to address the rejections under 35 U.S.C. §112 and 35 U.S.C. §103. The present response is believed to reflect and expand upon the content of this discussion. Reconsideration is respectfully requested.

The rejections of Claims 7, 8, and 22-26 under 35 U.S.C. §103(a) over WO 95/28853 (Muller et al) and of Claims 7, 8, and 22-26 under 35 U.S.C. §103(a) in view of U.S. Patent No. 6,045,819 (Takebe et al) in view of U.S. Patent No. 4,808,419 (Hsu) are obviated by amendment.

Applicants make no statement in regard to the propriety of these rejections. However, in order to expedite examination, Claim 7 has been amended to recite the limitations of previously pending Claim 14 (preparation of the vegetable protein material), which the Examiner has conceded as being free of these grounds of rejection.

In view of this amendment, it is requested that the Examiner acknowledge withdrawal of the rejections over Muller et al and Takebe et al in view of Hsu.

The rejection of Claims 7, 8, 14, 15, and 22-26 under 35 U.S.C. §103(a) over WO 95/28853 (Muller et al) and U.S. Patent No. 6,045,819 (Takebe et al) in view of U.S. Patent No. 5,888,561 (Niederberger et al) and U.S. Patent No. 4,808,419 (Hsu) are obviated in part by amendment and traversed in part.

The presently claimed invention relates to a method for producing hydrolyzed protein by subjecting a vegetable protein material containing saccharides to enzymatic hydrolysis, comprising:

(1) conducting cultivation of a koji mold in a submerged culture fermenter-type reaction vessel to obtain a fungal culture;

(2) mixing a dispersion of said vegetable protein material with said fungal culture to obtain a mixture; and

(3) subjecting said mixture to enzymatic hydrolysis first at a temperature ranging from 15 °C to 39 °C with aeration and agitation and then at a temperature ranging from 41 °C to 50 °C,

to obtain said hydrolyzed protein,

wherein a ratio of reducing sugars present in said hydrolyzed protein obtained is 5 % by weight or less based on the total solid content in said hydrolyzed protein, and

wherein the temperature is shifted from a temperature ranging from 15 °C to 39 °C to a temperature ranging from 41 °C to 50 °C when from 10% to 60% of the total period of time required for completion of the enzymatic hydrolysis has passed;

wherein each of (1) to (3) are in a liquid state,

wherein said vegetable protein material is prepared for said enzymatic hydrolysis by a process comprising:

(a) pulverizing a vegetable protein material which exists at least partially in a solid state to a size of 300 μm or less, to obtain pulverized vegetable protein material;

(b) dispersing said pulverized vegetable protein material in hot water at a temperature higher than 80 °C, to obtain a vegetable protein material dispersion;

(c) removing air bubbles from said vegetable protein material dispersion; and

(d) subjecting said vegetable protein material dispersion to sterilization immediately after said air bubbles have been substantially removed

and wherein *said method is in the absence of an added bacteriostatic substance.*

(Claim 7; *emphasis added*)

As described in the paragraph bridging page 4-5 of the specification, one of the objects of this invention is to “provide a process for producing hydrolyzed protein which is useful as a multi-purpose seasoning material or a multipurpose food material without contamination with germs even in the absence of a bacteriostatic substance, which process can be practiced in the industrial mass-production.”

Therefore, the claimed invention provides a method in which raw material (*e.g.*, wheat gluten or defatted soybean) is sterilized for a fermentation process in industrial mass-production, preferably, in the absence of an added bacteriostatic substance like salt, alcohol or acetic acid (see Claim 7).

In contrast, Muller et al disclose using an “enzymatic, salt-containing wheat gluten hydrolyzate having a high wheat gluten proportion in the form of a suspension, which is not heated intermediately and not filtered” (see Abstract, page 5, line 15 to page 6, line 9 (in particular, page 5, lines 19-21 and 29-32), and the Examples). This disclosure teaches away from the claimed invention in two ways: (1) Muller et al requires the addition of a salt (bacteriostatic agent), whereas the present invention excludes this addition, and (2) Muller et al specifically state that the wheat gluten hydrolyzate is *not* heated or filtered (*i.e.*, sterilized), whereas the claimed invention explicitly requires sterilization.

Applicants note that MPEP §2141.02 states: “A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303

(Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Therefore, for the two reasons cited above, Muller et al teach away from the claimed invention and, as such, there is no motivation to modify this disclosure to arrive at the present invention. Accordingly, Applicants note that the rejection over Muller et al in view of Niederberger et al and Hsu is no longer applicable and its withdrawal is requested.

Moreover, contrary to the Examiner's apparent assertion, the cited references (whether Muller et al, Hsu, Takebe et al, or Niederberger et al) do not disclose or suggests that each of (1) to (3) is in a liquid state. Applicants note that the methods disclosed by Muller et al (bread cubes; solid), Hsu (malt-yeast extract agar; semi-solid), Takebe et al (a pulse crop; solid), and Niederberger et al (wheat gluten cubes; solid) utilize solid-state cultures and/or semi solid-state cultures. Furthermore, when an Examiner maintains that there is an implicit teaching or suggestion in the prior art, "the Examiner should indicate where (page and line or figure) such a teaching or suggestion appears in the prior art." (*Ex parte Jones*, 62 USPQ2d 1206, 1208 (Bd. Pat. App. & Inter. 2001) (**copy enclosed**)). However, in the present application the Examiner has not indicated where, if at all, each claim limitation may be found in the art of record. Specifically, the Examiner has failed to show where in the art of record, any of Muller et al, Hsu, Takebe et al, or Niederberger et al disclose that (1) to (3) would be in a "liquid state."

As described in the paragraph bridging page 4-5 of the specification, one of the objects of this invention is to "provide a process for producing hydrolyzed protein which is useful as a multi-purpose seasoning material or a multipurpose food material without contamination with germs even in the absence of a bacteriostatic substance, which process can be practiced in the industrial mass-production." As such, the distinction between a "liquid state," "a semi-solid state," and a "solid state" culture is important. A "liquid state" is fluid,

free-flowing and homogeneous state, like a solution or dispersion, with a low viscosity. In contrast, a “semi-solid state” is non-fluid, non-flowing, not uniform, and possesses a heterogeneous composition.

Arising from the heterogeneous composition of “semi-solid state” or “solid state” cultures the resultant cultures are not uniform. As such, heat is not uniformly conducted in the culture. This lack of uniformity can give rise to local temperature differences that may result in microbial survival within the culture regions that have reduced temperatures. As a result, once the “sterilization” process is discontinued the surviving microbes may then repopulate the culture. Therefore, it is very difficult, or even unrealistic, to completely sterilize a “semi-solid state” or “solid state” culture on an industrial mass-production scale. (see paragraph 5 of the Declaration under 37 C.F.R. §1.132 **submitted herewith**).

In contrast, the culture in each of (1) to (3) is maintained as a “liquid state” culture. Owing to the homogeneity of the culture, it is possible to completely sterilize (even on an industrial mass-production scale) since the culture is fluid and heat of sterilization is evenly conducted in the culture.

Moreover, citing In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974), MPEP §2143.03 states: “To establish a prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” Applicants submit that the disclosures of Muller et al, Hsu, Takebe et al, and Niederberger et al, in any combination, fail to meet this requirement, and as such the artisan would have no direction to practice the claimed method, much less the advantageous properties flowing therefrom.

To further evidence the advantages obtained by the claimed invention (including the pre-hydrolysis processing step) over that of the art of record, Applicants **submit herewith** a Declaration under 37 C.F.R. §1.132. As clearly set forth in paragraph 6 of the Declaration

under 37 C.F.R. §1.132 (in particular Tables 1 and 2), the pre-hydrolysis processing provides unexpected advantages as compared to a method in which the pre-hydrolysis processing has been omitted (i.e., U.S. 6,045,819 (Takebe et al)). These experiments evince that by incorporating the pre-hydrolysis processing as in (a) to (d) of Claim 7 (above), the resultant protein hydrolyzate is free of contaminating microorganisms, possess a high protein activity, and possess excellent seasoning properties (e.g., taste and aroma), even in the absence of added bacteriostatic agents. At no point does the art of record disclose or suggest such advantages.

Accordingly, Applicants submit that the present invention would not be obvious in view of the disclosures of Muller et al, Hsu, Takebe et al, and Niederberger et al, in any combination. Accordingly, these references cannot affect the patentability of the present claims. Therefore, in view of the foregoing, Applicants submit that the obviousness rejections over the disclosures of Muller et al, Hsu, Takebe et al, and Niederberger et al (in any combination) are not longer tenable. Applicants request withdrawal of these grounds of rejection.

The rejection of Claims 7, 8, 14, 15, and 22-26 under 35 U.S.C. §112, second paragraph, has been obviated by amendment.

The Examiner has objected to the appearance of the term “the sample” as lacking sufficient antecedent basis in (1) to (3) of previously pending Claim 7. In order to clarify this claim and to clearly indicate that a “liquid state” is maintained in each of (1) to (3), Applicants have amended Claim 7 to remove the objectionable term.

In view of the foregoing, Applicants believe that the language of the claims are such that a person of ordinary skill in the art could interpret the metes and bound of the claims so

as to understand how to avoid infringement (MPEP §2173.02). Accordingly, Applicants submit that the presently pending claims are definite.

Therefore, Applicants request withdrawal of the claim objections pursuant to MPEP §2173.02.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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